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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/053,975	01/18/2002	Limin Li	STAN-216	5176		
75	90 06/29/2005		EXAM	INER		
PIPER RUDN		FETTEROLF,	FETTEROLF, BRANDON J			
SUPERVISOR,	PATENT PROSECUT	ION SERVICES				
1200 NINETER	ENTH STREET, N.W.	ART UNIT	PAPER NUMBER			
WASHINGTO	N, DC 20036-2412		1642			

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)						
	10/053,975	LI ET AL.						
Office Action Summary	Examiner	Art Unit						
	Brandon J. Fetterolf, PhD	1642						
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status								
1) Responsive to communication(s) filed on 26 A	<u>pril 2005</u> .	,						
2a)⊠ This action is FINAL . 2b)□ This	action is non-final.							
3) Since this application is in condition for allowar	nce except for formal matters, pro	secution as to the merits is						
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.						
Disposition of Claims		·						
4)⊠ Claim(s) <u>1,4-16,22-25,31,32 and 37-45</u> is/are p	pending in the application.							
4a) Of the above claim(s) <u>7-16,22-25,31,32,44</u>	<u>and 45</u> is/are withdrawn from con	sideration.						
5) Claim(s) is/are allowed.								
6)⊠ Claim(s) <u>1, 4-6 and 43</u> is/are rejected. 7)□ Claim(s) is/are objected to.								
8) Claim(s) are subject to restriction and/o	r election requirement							
	olocion roquiroment.							
Application Papers								
9) The specification is objected to by the Examine								
10) The drawing(s) filed on is/are: a) according to the second state of the seco	, , , , , , , , , , , , , , , , , , , ,							
Applicant may not request that any objection to the								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority under 35 U.S.C. § 119								
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	-(d) or (f).						
a) All b) Some * c) None of:	s have been received							
Certified copies of the priority documents Certified copies of the priority documents		on No						
 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage 								
application from the International Bureau (PCT Rule 17.2(a)).								
* See the attached detailed Office action for a list of the certified copies not received.								
	•							
Attachment(s)								
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4)							
 2) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 	5) Notice of Informal P	atent Application (PTO-152)						
Paper No(s)/Mail Date	6)							

Application/Control Number: 10/053,975

Art Unit: 1642

Li et al.

Response to the Amendment

The Amendment filed on 04/26/2005 in response to the previous Non-Final Office Action (01/26/2005) is acknowledged and has been entered.

Claims 2-3, 17-21, 26-30 and 33-36 have been cancelled.

Claims 1, 4-16, 22-25, 31-32 and 37-45 are currently pending.

Claims 7-16, 22-25, 31-32 and 44-45 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1, 4-6 and 43 are currently under consideration.

The Terminal Disclaimer filed on 4/26/2005 has been reviewed and accepted.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 1 and 43 remain rejected and amended claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record in the prior Office Action (01/26/2005, pages 4-6) and for the reasons set forth below.

In reference to the previous action which held that the specification only reasonably conveys antibodies that bind to one species of polypeptide comprising a ubiquitination domain referred to as human TSG101 consisting of the amino acid sequence set forth in SEQ ID NO: 1, but not antibodies to any functional fragment thereof, Applicant's assert (Page 8) that the specification provides ample support for antibodies binding to any functional fragment of the ubiquitination-regulating domain of human TSG101. For example, Applicants submit that the specification provides the complete sequence of the ubiquitination-regulating domain of human TSG101 (page 24, last paragraph) and tested deletion mutants of human TSG101 (page 30, 2nd paragraph, and Fig. 3a). Thus, Applicants believe that with this information, one skilled in the art would be able to identify any functional fragment of the ubiquitination-regulating domain without undue

experimentation. Moreover, Applicants argue that the specification further satisfies the written description requirement by providing a sufficient number of species (i.e., the fragments listed on page 24, last paragraph of the specification) falling within the scope of the genus (i.e. the functional fragment of the ubiquitination-regulating domain of human TSG101). These arguments have been carefully considered but are not found persuasive.

First, the previous rejection was based on whether the specification reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed genus of polypeptides comprising an ubiquitination-regulating domain or any functional fragment thereof. Thus, while Applicants contend that the specification provides "ample" support for any functional fragment (page 24, last paragraph, page 30, 2nd paragraph, and Figure 3A of the specification), Applicants have not clearly established that they were in possession of any and/or all functional fragments. Although the Examiner concedes that the specification provides the complete sequence of the ubiquitination-regulating domain of human TSG101 (page 24, last paragraph) and deletion fragments of human TSG101 (Figure 3A), the specification does not appear to provide a written description for any and/or all functional fragments of a polypeptide comprising an ubiquitination-regulating domain comprising the amino acid sequence of SEQ ID NO: 1. For example, the specification provides a number of fragments (page 24, last paragraph) of the amino acid sequence of SEQ ID NO: 1. However, the specification does not appear to describe any structural features which are common to the individual fragments which would allow the fragment to function as presently claimed. Therefore, Claims 1 and 43 remain rejected and amended claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Amended claims 1, 4 and 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (IDS, US 5,891,668, 1999) and claims 1, 4-6 and 43 remain rejected under 35 U.S.C. 102(b) as being anticipated by Brie et al. (US 5,892,016, 1999) for the reasons of record in the prior Office Action (01/26/2005, pages 6-8) and for the reasons set forth below.

In reference to the previous action which held that Li et al. (pages 6-7) teaches antibodies which specifically bind to the coiled domain, leucine zipper and proline rich domains of TSG101, Applicants assert that Li generally describes antibodies to normal or mutated forms of human

TSG101. In reference to the previous action which held that Brie et al (page 7-8) teaches antibodies to a purified protein having 100% sequence identity to the amino acid sequence set forth in SEQ ID NO: 1, Applicants contend that Brie generally describes the complete sequence of human TSG101 and antibodies that bind specifically to the polypeptides. Thus, Applicants submit that Li and Brie describe a genus of antibodies that bind to the full length human TSG101, while the present invention discloses a species of that genus (i.e., antibodies to the ubiquitination-regulating domain of human TSG101) and therefore, a genus does not always anticipate a claim to a species within the genus. Consequently, Applicants argue that since neither Li nor Brie disclose the ubiquitinationregulating domain of human TSG101, one skilled in the art would not be able to "at once envisage" antibodies binding to the ubiquitination-regulating domain based on the teachings of Li or Brie. Moreover, Applicants contend that the binding to the ubiquitination domain is not an inherent characteristic of the antibodies of Li or Brie because in order to establish inherency, Applicants content that "the Examiner has to demonstrate that the missing descriptive matter must be necessarily present in the prior art. In re Robertson, 49 USPQ2d 1949, 1950-1951 (Fed Cir. 1999)." (hereinafter "Robertson") Furthermore, Applicant's assert that antibodies to the ubiquitination-regulating domain are not necessarily present in antibodies that bind to the full length TSG101. As such, Applicants content that the mere fact that some anti-TSG101 antibody may bind to the ubiquitination -regulating domain is not enough to establish inherency. These arguments have been carefully considered but are not found persuasive.

First, the previous rejection was based on whether the prior art taught an isolated antibody that binds specifically to a polypeptide comprising an ubiquitination-regulating domain, or a functional fragment thereof, of a human TSG101 protein comprising the amino acid sequence of SEQ ID NO: 1. Thus, while applicants argue that the prior arts antibodies are to a genus of antibodies that bind to the <u>full length human TSG101</u> (emphasis added) and not the species as presently claimed, Applicants have not provided a patentable difference between the antibody presently claimed and the ones disclosed in the prior art. In the instant case, the claims are drawn to an isolated antibody that binds to a polypeptide <u>comprising</u> (emphasis added) an ubiquitination-regulating domain, or a functional fragment thereof, of a human TSG101 protein <u>comprising</u> (emphasis added) the amino acid sequence recited in SEQ ID NO: 1. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is

inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re-Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Thus, there does not appear to be a patentable difference between an antibody which binds to a polypeptide fragment (100% identical from amino acids 11 to 390 of SEQ ID NO: 1) of the amino acid sequence recited in SEQ ID NO: 1 (Li, US 5,891,668, see sequence comparison) or an antibody which binds to a polypeptide that is 100% identical (see sequence comparison) to a polypeptide comprising the amino acid sequence recited in SEQ ID NO: 1, wherein the ubiquitination-regulating domain may comprise amino acid residues 50-140, 1-140 or 140-250 of SEQ ID NO: 1. Moreover, while Applicants assert that the binding to the ubiquitination-regulating domain is not an inherent characteristic of the antibodies of Li or Brie, Applicants have not provided any factual evidence that the claimed product is different from the prior art. Furthermore, the Examiner agrees with Applicants assertion that the initial burden is on the Examiner to demonstrate that the missing descriptive matter must be necessarily present in the prior art. However, it does not appear that Applicants interpretation of Robertson is relevant to the instantly claimed invention. In Robertson, the Board found that the Board of Patent Appeals and Interferences improperly rejected an application claim for fastening and disposal system for diapers on grounds that the prior art reference inherently contained all elements of a claim, since the board failed to recognize that the third (emphasis added) mechanical fastening means of the application claim, used to secure the diaper for disposal, was separate from and independent of the two other means used to attach the diaper to the wearer (emphasis added), and since the boards theory that the two fastening devices in the reference were capable of being intermingled to perform the same function as the third and first the elements in the applications claim rest upon mere probability or possibility that is insufficient to establish inherency. Thus, it appears that the prior arts reference did not teach the three different mechanical devices. In the instant case, the claims are not drawn to three different mechanical devices, but to an isolated antibody that binds to a polypeptide

comprising (emphasis added) an ubiquitination-regulating domain, or a functional fragment thereof, of a human TSG101 protein comprising (emphasis added) the amino acid sequence recited in SEQ ID NO: 1. The prior art teaches an antibody which binds to a polypeptide (100% identical from amino acids 11 to 390 of SEQ ID NO: 1) comprising a ubiquitination-regulating domain comprising the amino acid sequence recited in SEQ ID NO: 1 (Li, US 5,891,668, see sequence comparison) and an antibody which binds to a polypeptide that is 100% identical (see sequence comparison) to a polypeptide comprising a ubiquitination-regulating domain comprising the amino acid sequence recited in SEQ ID NO: 1, wherein the ubiquitination-regulating domain may comprise amino acid residues 50-140, 1-140 or 140-250 of SEQ ID NO: 1. Thus, the claimed antibody appears to be the same as the prior art. As stated in the prior Office Action (pages 7 and 8), the office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Therefore, amended claims 1, 4 and 6. remain rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (IDS, US 5,891,668, 1999) and claims 1, 4-6 and 43 remain rejected under 35 U.S.C. 102(b) as being anticipated by Brie et al. (US 5,892,016, 1999)

Therefore, NO claim is allowed

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD Examiner Art Unit 1642

BF

SUPERVISORY PATENT EXAMINER

Please attach + Ind to Applicant

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SUMMARIES

Result Query No. Score Match Length DB ID Description 1 2047 100.0 390 2 US-08-786-999-1 Sequence 1, Appl 2 2047 100.0 390 4 US-09-216-387-1 Sequence 1, Appl 3 2047 100.0 390 4 US-09-886-319A-2 Sequence 2, Appl 4 2047 100.0 403 4 US-09-949-016-11251 Sequence 11251, 5 2002 97.8 380 1 US-08-585-758A-4 Sequence 4, Appl			%				
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27	148.5	7.3	148	4	US-09-461-325-453	Sequence 453, App
28	148.5	7.3	148	4	US-10-012-542-453 US-10-115-123-453	Sequence 453, App
29 30	148.5 147	7.3 7.2	148 489	4	US-09-949-016-7068	Sequence 453, App Sequence 7068, Ap
31	147	7.2	489	4	US-09-949-016-7069	Sequence 7069, Ap
32	142	6.9	557	4	US-09-949-016-7621	Sequence 7621, Ap
33	141	6.9	905	ż	US-08-574-959A-9	Sequence 9, Appli
34	141	6.9	905	3	US-09-357-014-9	Sequence 9, Appli
35	141	6.9	1135	2	US-08-574-959A-7	Sequence 7, Appli
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39	130	6.4	543	4	US-09-535-008-63	Sequence 63, App]
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51 52	130 127	6.4 6.2	1682 1184	4	US-09-535-008-73 US-09-266-225D-18	Sequence 73, Appl Sequence 18, Appl
53	127	6.2	1185	3	US-09-041-886-23	Sequence 23, Appl
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60 61	125.5 , 125.5	$\begin{array}{c} 6.1 \\ 6.1 \end{array}$	408 408	1	US-07-609-716-65 US-08-475-411A-65	Sequence 65, Appl Sequence 65, Appl
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                                                   4 US-09-690-454-136
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5.7
5.7
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                                                                                                    Sequence 2, Appli
Sequence 9, Appli
Sequence 21, Appl
Sequence 66, Appl
Sequence 33, Appl
Sequence 66, Appl
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4 US-09-289-578-9

4 US-09-331-347C-21

1 US-07-609-716-66

1 US-08-642-255-33

3 US-08-475-411A-66
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RESULT 7
US-08-670-274B-4
; Sequence 4, Application US/08670274B; Patent No. 5891668
    GENERAL INFORMATION:
APPLICANT: LI, Limin
APPLICANT: COHEN, Stanley N
TITLE OF INVENTION: MAMMALIAN TUMOR SUSCEPTIBILITY GENES AND
        TITLE OF INVENTION: THEIR USES
        NUMBER OF SEQUENCES: 20
        CORRESPONDENCE ADDRESS:
         ADDRESSEE: FISH AND RICHARDSON, P.C. STREET: 2200 SAND HILL ROAD
           CITY: MENLO PARK
STATE: CA
COUNTRY: USA
           ZIP: 94025
        COMPUTER READABLE FORM:
        MEDIUM TYPE: Floppy disk
COMPUTER: IBM PC compatible
OPERATING SYSTEM: PC-DOS/MS-DOS
           SOFTWARE: PatentIn Release #1.0, Version #1.30
        CURRENT APPLICATION DATA:
          APPLICATION NUMBER: US/08/670,274B
           FILING DATE: June 13, 1996
           CLASSIFICATION: 435
        ATTORNEY/AGENT INFORMATION:
NAME: SHERWOOD, Pamela J.
           REGISTRATION NUMBER: 36,677
    TELECOMMUNICATION INFORMATION:
TELEPHONE: 415-781-1989
TELEFAX: 415-398-3249
TELEX: 910 277299
INFORMATION FOR SEQ ID NO: 4:
        SEQUENCE CHARACTERISTICS:
           LENGTH: 380 amino acids
            TYPE: amino acid
            TOPOLOGY: linear
; MOLECULE TYPE: protein US-08-670-274B-4
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us-10-053-975a-1.rai

us-09-949-016-8707

Sequence 8707, Ap

120

us-10-053-975a-1.rai

Quer	y Match		97.8%;	Score	2002;	DB 2;	Length 3	80;		
Best Matc	hes 380	imilarity ; Conservat	100.0%;	0; Mis	matche	s 0;	Indels	0;	Gaps	0;
Qy	11	MVSKYKYRDLT\	/RETVNVI	TLYKDL	(PVLDSY	VFNDGSSR	ELMNLTGT	IPVPYR	GNTYNI	70
Db	1	MVSKYKYRDLT\	/RETVNVI	TLYKDL	(PVLDSY	VFNDGSSR	ELMNLTGT	IPVPYR	GNTYNI	60
Qy	71	PICLWLLDTYP	YNPPICFV	/KPTSSM	TIKTGKH	IVDANGKIY	LPYLHEWK	HPQSDL	LGLIQV	130
Dρ	61	PICLWLLDTYP	YNPPICFV	/KPTSSM	riktgkh	IVDANGKIY	LPYLHEWK	HPQSDL	ĹĠĹİQV	120
Qy	131	MIVVFGDEPPVI	FSRPISAS	SYPPYQA ⁻	TGPPNTS	SYMPGMPGG	ISPYPSGY	PPNPSG	YPGCPY	190
Db	121	MIVVFGDEPPV	FSRPISAS	YPPYQA	TGPPNTS	SYMPGMPGG	SISPYPSGY	PPNPSO	YPGCPY	180
Qy	191	PPGGPYPATTS:	SQYPSQPF	PVTTVGP:	SRDGTIS	SEDTIRASL	.ISAVSDKL	RWRMKE	EMDRAQ	250
Db	181	PPGGPYPATTS	SQYPSQPF	VTTVGP:	SRDGTIS	SEDTIRASL	.isAVSDKL	.RWRMKE	ĖMDRAQ	240
Qy	251	AELNALKRTEE	DLKKGHQK	KLEEMVT	RLDQEVA	AEVDKNIEL	LKKKDEEL	SSALE	MENQSE	310
Db	241	AELNALKRTEE	DLKKGHQ	KLEEMVT	RLDQEVA	AEVDKNIEL	LKKKDEEL	.SSALĖ	MENQSE	300
Qy	311	NNDIDEVIIPT	APLYKQII	LNLYAEE	NAIEDT:	IFYLGEALF	RRGVIDLDV	/FLKHVF	RLLSRKQ	370
Db	301	NNDIDEVIIPT	APLYKQII	LNLYAEE	NAIEDT:	İFYLGEALF	RGVIDLDV	/FĽKHVI	ŔĹĹŚŔŔQ	360
Qy	371	FQLRALMQKAR	KTAGLSDI	LY 390						
Db	361	FQLRALMQKAR								